

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MERCK & CO., INC.
126 EAST LINCOLN AVENUE
RAHWAY, NJ 07065-0907

PCT REC'D 03 JAN 2006
WIPO
PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

		Date of mailing (day/month/year) 23 DEC 2005
Applicant's or agent's file reference PCT 21668Y		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US05/09562	International filing date (day/month/year) 22 March 2005 (22.03.2005)	Priority date (day/month/year) 26 March 2004 (26.03.2004)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 31/445 and US Cl.: 514/319, 326, 397		
Applicant MERCK & CO., INC.		

1. This opinion contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the opinion
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 03 December 2005 (03.12.2005)	Authorized officer Sreenivasan Padmanabhan <i>J. Roberto</i> Telephone No. (571) 272-1600
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Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/09562

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 the international application in the language in which it was filed
 a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material
 on paper
 in electronic form
 - c. time of filing/furnishing
 contained in the international application as filed.
 filed together with the international application in electronic form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/09562

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-15</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-15</u>	NO
Industrial applicability (IA)	Claims <u>1-15</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-15 lack novelty under PCT Article 33(2) as being anticipated by DURANT et al. (US 5,486,526 A1). DURANT et al. teaches the histamine H3-receptor antagonist useful for the treatment of a subject suffering from Parkinson's diseases, tardive dyskinesia and hyperkinesias. (abstract, column 9, lines 11-48, particularly, line 40-45).

Claims 1-15 lack an inventive step under PCT Article 33(3) as being obvious over DURANT et al. (US 5,486,526 A1). DURANT et al. teaches the histamine H3-receptor antagonist useful for the treatment of a subject suffering from Parkinson's diseases, tardive dyskinesia and hyperkinesias. (abstract, column 9, lines 11-48, particularly, line 40-45). Applicant's limitation of the tremor associated with Parkinson's disease is obviously eliminated upon treatment of the same disorder, i.e. Parkinson's disease, tardive dyskinesia and hyperkinesias.

Claims 1-15 meet the criteria set out in PCT Article 33(4), because the method for treating, controlling, ameliorating or reducing the risk of a movement disorder in a patient in need thereof that comprises administering to the patient a therapeutically effective amount of a histamine H3-inverse agonist or a histamine H3 antagonist, or a pharmaceutically acceptable salt thereof has an industrial applicability in pharmaceutical art.

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